

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH**

LINDA P. SMITH,

Plaintiff,

v.

XAVIER BECERRA, in his official  
capacity as Secretary of Health and  
Human Services,

Defendant.

Case No. 1:21-cv-47 (CMR)

**RESPONSE TO COMPLAINT**

Pursuant to Local Civil Rule 7-4(a)(2)(B), the Secretary of Health and Human Services makes the following short and plain statement in response to Plaintiff's complaint:

The complaint challenges a decision by the Medicare Appeals Council, Docket No. M-19-1973, denying coverage under Medicare Part B for three claims. The first claim is for a MiniMed 630G system. This device is a durable insulin pump, which is covered as durable medical equipment under the Medicare statute and regulations. The Medicare Appeals Council erred in denying coverage for this item.

The second and third claims are for disposable sensors used with the insulin pump, which also functions as a continuous glucose monitor. Coverage for the disposable sensors was denied, because the continuous glucose monitor function of the device does not satisfy CMS Ruling 1682-R, which interprets the Medicare statute and regulations as applied to continuous glucose monitors. This denial was also erroneous, because it failed to consider an important aspect of the problem: whether the sensors were reasonable and necessary for the operation of the insulin pump function of the device, which uses sensor data to determine when to automatically shut off the flow of insulin.

Because the challenged decision was erroneous, this Court should enter judgment in favor of Plaintiff and remand to the Secretary for payment of the claim for the insulin pump, and determination of whether the sensors should be covered as reasonable and necessary for the operation of the insulin pump.

Dated: June 7, 2021

Respectfully submitted,

BRIAN M. BOYNTON  
Acting Assistant Attorney General

MICHELLE BENNETT  
Assistant Director, Federal Programs Branch

/s/ James Bickford  
JAMES BICKFORD  
Trial Attorney (N.Y. Bar No. 5163498)  
United States Department of Justice  
Civil Division, Federal Programs Branch  
1100 L Street, NW  
Washington, DC 20530  
James.Bickford@usdoj.gov  
Telephone: (202) 305-7632  
Facsimile: (202) 616-8470

*Counsel for Defendant*